

Serial No. 09/539,748

Docket No. R2005-700010

Listing of Claims

1. (Withdrawn) A system for soft tissue reconstructive surgery comprising:
a soft tissue fixation device, wherein said fixation device affixes at least two intact anatomic soft tissue structures; and
an applicator that inserts the soft tissue fixation device from a first anatomic structure into a second anatomic structure and fixatingly positions said soft tissue fixation device within said first and said second anatomic structures.
2. (Withdrawn) The system of claim 2, wherein said first anatomic structure is suspended from said second anatomic structure by a positioning of said soft tissue fixation device.
3. (Withdrawn) The system of claim 1 wherein the first anatomic structure lies in contiguity with the second anatomic structure in a native anatomic state.
4. (Withdrawn) The system of claim 1, wherein the soft tissue fixation device further comprises a means for adjusting tightness of affixation of said first anatomic structure to said second anatomic structure after the soft tissue fixation device has been positioned.
5. (Withdrawn) The system of claim 1, wherein the soft tissue fixation device comprises a screw.
6. (Withdrawn) The system of claim 1, wherein the soft tissue fixation device comprises a ring.
7. (Withdrawn) The system of claim 1, wherein the soft tissue fixation device comprises an anchor.

Serial No. 09/539,748

Docket No. R2005-700010

8. (Withdrawn) The system of claim 1, wherein the soft tissue fixation device comprises a barb.
9. (Withdrawn) The system of claim 8, wherein the barb is flexible.
10. (Withdrawn) The system of claim 9, wherein the at least one flexible barb springs from a closed position to an open position when it is positioned within the second anatomic structure.
11. (Withdrawn) The system of claim 9, wherein the at least one flexible barb is urged from the closed position to the open position by the applicator.
12. (Withdrawn) The system of claim 9, wherein the at least one flexible barb is urged from the closed position to the open position by proximally directed traction.
13. (Withdrawn) The system of claim 1, wherein the soft tissue fixation device comprises a staple.
14. (Withdrawn) The system of claim 13, wherein the applicator alters the shape of the staple after said staple is driven from the first anatomic structure into the second anatomic structure, thereby affixing said staple in said at least two anatomic structures.
15. (Withdrawn) The system of claim 1, wherein the soft tissue fixation device is coated with a substance capable of promoting epithelialization.
16. (Withdrawn) The system of claim 15, wherein the substance is selected from the group consisting of collagen, growth factor and adhesion ligand.
17. (Withdrawn) The system of claim 1, wherein the soft tissue fixation device is provided with a coating that stimulates tissue in growth.

Serial No. 09/539,748

Docket No. R2005-700010

18. (Withdrawn) The system of claim 1, wherein a surface of the soft tissue device is treated to stimulate collagen deposition.
19. (Withdrawn) The system of claim 1, wherein the soft tissue fixation device is formed at least in part from a bioabsorbable material.
20. (Withdrawn) The system of claim 1, wherein the applicator is adapted for inserting at least two soft tissue fixation devices simultaneously.
21. (Withdrawn) The system of claim 1, further comprising a remover to extricate the soft tissue fixation device from said at least two anatomic structures.
22. (Withdrawn) The system of claim 1 wherein the soft tissue fixation device may be removed from the at least two anatomic structures by manipulation.
23. (Withdrawn) The system of claim 1, wherein the soft tissue fixation device comprises adjustable ratchets.
24. (Withdrawn) The system of claim 1, further comprising a template that guides a positioning of the soft tissue fixation device.
25. (Withdrawn) A method for soft tissue reconstruction comprising:
 - providing a soft tissue fixation device and an applicator,
 - identifying at least two anatomic structures suitable for coaptation,
 - wherein coaptation is determined to be an effective mechanism for soft tissue reconstruction,
 - stabilizing the at least two anatomic structures in surgical proximity,
 - driving the soft tissue fixation device from a first anatomic structure into a second anatomic structure, and

Serial No. 09/539,748

Docket No. R2005-700010

engaging the soft tissue fixation device within the second anatomic structure.

26. (Withdrawn) The method of claim 25, further comprising
providing a remover for atraumatically removing the soft tissue fixation device from the at least two anatomic structures,
examining a position of the soft tissue fixation device within the first and the second anatomic structure to determine whether said soft tissue fixation device is malpositioned, and
employing the remover to remove the soft tissue fixation device that is malpositioned.

27. (Withdrawn) A method for supporting a soft tissue structure, comprising:
providing a soft tissue fixation device and an applicator,
identifying at least two anatomic structures physiologically adapted for supporting the soft tissue structure,
positioning a first anatomic structure in juxtaposition to a second anatomic structure, thereby to support the soft tissue structure, and
affixing the first anatomic structure to the second anatomic structure with the soft tissue fixation device inserted by the applicator.

28. (Withdrawn) The method of claim 27, further comprising
positioning a template dimensionally adapted for guiding a placement of the soft tissue fixation device, and
directing the soft tissue fixation device into the first anatomic structure in accordance with the template.

29. (Withdrawn) The method of claim 27, further comprising examining a position of the tissue fixation device within the at least two anatomic structures and removing the soft tissue fixation device that is malpositioned.

Serial No. 09/539,748

Docket No. R2005-700010

30. (Withdrawn) The method of claim 27, wherein the soft tissue fixation device is selected from the group consisting of staples, screws, barbed tacks, and anchors.
31. (Withdrawn) The method of claim 29, further comprising providing a remover to extricate the fixation device from the at least two anatomic structures, and employing the remover to remove the soft tissue fixation device that is malpositioned.
32. (Withdrawn) The method of claim 29, wherein the soft tissue fixation device that is malpositioned is removed by traction.
33. (Withdrawn) The method of claim 27, wherein the soft tissue structure comprises the rectum, wherein the first anatomic structure is a lateral vaginal sulcus and wherein the second anatomic structure comprises the arcus tendineus fascia of the pelvis or the levator ani.
34. (Withdrawn) The method of claim 27, wherein the soft tissue structure is selected from the group consisting of the bladder, the urethra, the vaginal vault and the uterus.
35. (Withdrawn) The method of claim 27, further comprising identifying at least one anatomic structure by a diagnostic modality selected from the group consisting of MRI, fluoroscopy, CT scan, conventional radiology, ultrasound, laparoscopy and endoscopy.
36. (Withdrawn) The method of claim 27, further comprising guiding the fixation device into at least one anatomic structure by a modality selected from the group consisting of MRI, fluoroscopy, CT scan, conventional radiology, ultrasound, laparoscopy, endoscopy, direct vision and intraoperative palpation.
37. (Withdrawn) A soft tissue fastener system, comprising
means for penetrating an intact outer wall of a first soft tissue
means for penetrating a second soft tissue, and

Serial No. 09/539,748

Docket No. R2005-700010

means for affixing said first soft tissue to said second soft tissue

38. (Withdrawn) The system of claim 37, further comprising a means for detaching an affixation between said first soft tissue and said second soft tissue without disturbing physiological integrity of said first and second soft tissues.

39. (Previously presented) A method of surgical paravaginal repair, comprising:

placing a soft tissue fixation device vaginally through an insertion device adapted for inserting the soft tissue fixation device; and

approximating at least one of the superior lateral sulci and inferior lateral sulci to the lateral pelvic sidewall without exposing the lateral pelvic sidewall through a surgical incision in a vaginal wall.

40. (Withdrawn) A method for diagnosing a pelvic floor defect, comprising:

providing a template adapted for insertion in a vagina, wherein said template replicates forces applied during a paravaginal repair;

inserting the template into the vagina; and

observing whether the pelvic floor defect is reduced.

41. (Previously presented) A method of surgical repair using a soft tissue fixation device and an insertion device, wherein the surgical repair is one of a paravaginal repair and a vaginal repair, the method comprising:

placing the soft tissue fixation device vaginally through the insertion device; and

approximating a vaginal epithelium to at least one of a lateral pelvic sidewall and a sacrospinous ligament without exposing at least one of the lateral pelvic sidewall and the sacrospinous ligament through a surgical incision in the vaginal epithelium.

42. (Previously presented) The method of claim 41, further comprising:

Serial No. 09/539,748

Docket No. R2005-700010

positioning a template dimensionally adapted for guiding a placement of the soft tissue fixation device in a vagina; and
directing the soft tissue fixation device into the vagina in accordance with the template.

43. (Previously presented) The method of claim 41, further comprising:

examining a position of the tissue fixation device within the vaginal epithelium and a tissue approximated thereto; and
removing the soft tissue fixation device when the soft tissue fixation device is malpositioned.

44. (Previously presented) The method of claim 43, further comprising:

providing a remover to extricate the fixation device from the vaginal epithelium and the tissue approximated thereto; and
employing the remover to remove the soft tissue fixation device that is malpositioned.

45. (Previously presented) The method of claim 43, wherein the soft tissue fixation device that is malpositioned is removed by traction.

46. (Previously presented) The method of claim 41, wherein the soft tissue fixation device is selected from a group including sutures, suture/cleat combinations, suture/lock combinations, staples, screws, barbed tacks, and anchors.

47. (Previously presented) The method of claim 41, wherein a lateral vaginal sulcus is approximated to at least one of an arcus tendineus fascia of the pelvis and a structure of a levator ani for paravaginal repair of a rectocele.

48. (Previously presented) The method of claim 47, wherein the structure of the levator ani includes at least one of a fascia and a muscle.

Serial No. 09/539,748

Docket No. R2005-700010

49. (Previously presented) The method of claim 41, wherein the structural repair includes a soft tissue repair selected from a group including a cystocele, urethrocele, vaginal vault prolapse, rectocele, and uterine prolapse.
50. (Previously presented) The method of claim 41, further comprising identifying the soft tissue to be repaired by a diagnostic modality selected from a group consisting of MRI, fluoroscopy, CT scan, conventional radiology, ultrasound, laparoscopy and endoscopy.
51. (Previously presented) The method of claim 41, further comprising guiding the fixation device into at least one anatomic structure by a modality selected from a group consisting of MRI, fluoroscopy, CT scan, conventional radiology, ultrasound, laparoscopy, endoscopy, direct vision and intraoperative palpation.
52. (Previously presented) A method of soft tissue repair, wherein the repair is at least one of a paravaginal repair and a vaginal repair, the method comprising:
penetrating an intact outer wall of a first soft tissue;
penetrating a second soft tissue; and
affixing said first soft tissue to said second soft tissue without exposing one of the first tissue and the second tissue through a surgical incision in the other tissue.
53. (Previously presented) The method of claim 39, in which at least one of the superior lateral sulci and inferior lateral sulci is approximated to the lateral pelvic sidewall without making an incision.
54. (Previously presented) The method of claim 41, in which the vaginal epithelium is approximated to at least one of a lateral pelvic sidewall and a sacrospinous ligament without making an incision.

Serial No. 09/539,748

Docket No. R2005-700010

55. (Previously presented) The method of claim 52, in which the first tissue is affixed to the second tissue without making an incision.